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10/516,395	12/02/2004	Tokumi Ishikawa	2004 1847A	5078

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EXAMINER	
MATNEY, BROOKE MARIE	
ART UNIT	**PAPER NUMBER**
3763	

NOTIFICATION DATE	DELIVERY MODE
09/20/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/516,395	ISHIKAWA ET AL.	
	Examiner	Art Unit	
	Brooke M. Matney	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,15-17 and 21-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,15-17 and 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/5/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. This office action is responsive to the amendment filed on 7/6/2010. As directed by the amendment: claims 1-10 and 15-17 have been amended, claims 11-14 and 18-20 have been canceled, and new claims 21-23 have been added. Thus, claims 1-10, 15-17, and 21-23 are presently pending in the application. In light of the amendments to claims 2 and 5, the rejections of claims 2 and 5 under 35 USC 112 have been withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-10, 16-17, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by *Lippe et al.* [U.S. Patent No. 6,171,276 B1].

As to claim 1, *Lippe et al.* discloses an automatic administration instrument for medical use for injecting a drug solution filled in a syringe, said automatic administration instrument comprising: a body (housing 2, Fig. 1A) for housing the syringe (container 3) and an injection needle (4); a first motor for driving the syringe within said body in a direction toward the tip of the injection needle such that the injection needle protrudes from said body (Col. 15, ll. 4-17, teaches that separate electrical motor means should be present for the function

of the penetration means); a second motor for operating the syringe to administer the drug solution (motor 7); a switch (switch 11) provided on said body, said switch being operated by pressing a part of the exterior of said body against a body region of a patient to which the drug solution is to be administered (Col. 16, ll. 1-5), wherein said switch activates said first motor such that the injection needle protrudes from said body to perform needle insertion into said body region (Col. 15, ll. 4-18, teaches that electrical motor means can be used as penetration means and are controllable by electric means), and thereafter activates said second motor to administer the drug solution (Col. 16, ll. 26-29).

As to claim 2, *Lippe et al.* discloses an automatic administration instrument for medical use as defined in Claim 1 wherein, after a detection means (cover structure 10) detects that the administration instrument body is removed from the body region, the driving means is operated so that the injection needle that protrudes from the body to be inserted in the body region is housed in the administration instrument body (Col. 16, ll. 5-8). *Lippe et al.* teaches that the cover can be biased with a spring, so when the body is removed from the region the detection means will no longer complete the circuit and the injection needle will be retracted into the housing.

As to claim 2, *Lippe et al.* discloses further comprising a detection means (cover structure 10) for detecting that administration of the drug solution is completed and/or that said body is removed from the body region, wherein the first motor is operated so that the injection needle is retracted into said body after

said detection means detects that administration of the drug solution is completed and/or that said body is removed from the body region (Col. 15, ll. 4-17). *Lippe et al.* teaches that separate electrical motor means (the first motor) can be used for penetration means with return means.

As to claim 3, *Lippe et al.* discloses wherein a speed of inserting the injection needle or a speed of pulling out the injection needle is variable (Col. 12, ll. 34-43).

As to claim 4, *Lippe et al.* discloses wherein a speed at which the drug solution is administered by said second motor is variable (Col. 11, l. 66- Col. 12, l. 7). *Lippe et al.* teaches different delivery modes of operation that could deliver at different speeds.

As to claim 5, *Lippe et al.* discloses further comprising: an inner case (cover 8) that is slidably provided in an outer case (housing 2) of said body, said inner case being configured to attach to the injection needle and the syringe (Fig. 1A), wherein said first motor drives the syringe by sliding said inner case in said outer case (Col. 11, 15, ll. 4-17), and wherein said first motor is operated by said switch to automatically insert the injection needle into the body region of the patient by sliding said inner case so that the injection needle protrudes from said outer case (Col. 11, 15, ll. 4-17). If the electrical motor means taught by *Lippe et al.* for penetration were used with the embodiment of Fig. 1A, it would drive the syringe in this manner.

As to claim 6, *Lippe et al.* discloses wherein said inner case slides such that the injection needle protruding from said outer case is retracted into said outer case to automatically remove the injection needle (Col. 16, ll. 5-8). *Lippe et al.* teaches that the cover can be biased with a spring, so when the inner case is slid away from the patient the injection needle is removed and housing in the outer case.

As to claim 7, *Lippe et al.* discloses wherein said switch is a detection switch (cover switch 10) for detecting whether said body contacts the body region to which the drug solution is to be administered (Col. 16, l. 8-29).

As to claim 8, *Lippe et al.* discloses wherein insertion of the injection needle is enabled when said detection switch detects that said administration instrument contacts the body region to which the drug solution is to be administered (Fig. 1C, Col. 16, ll. 12-16).

As to claim 9, *Lippe et al.* discloses wherein administration of the drug solution is stopped when said detection switch detects during administration of the drug solution that said administration instrument does not contact the body region to which the drug solution is to be administered (Col. 16, ll. 8-12). When the detection switch detects that the administration instrument is not in contact with the body region, the circuit is broken and the motor is stopped.

As to claim 10, *Lippe et al.* discloses wherein the injection needle is retracted into said body when said detection switch detects during insertion of the injection needle that the administration instrument does not contact the body

region to which the drug solution is to be administered (Col. 16, ll. 5-8). When the administration instrument does not contact the body region, the detection switch moves with the cover and the injection needle moves away from the body so that it is no longer in contact with the body region and is protected by the cover.

As to claim 16, *Lippe et al.* discloses wherein a speed of inserting the injection needle or a speed of pulling out the injection needle is variable (Col. 12, ll. 34-43).

As to claim 17, *Lippe et al.* discloses wherein a speed at which the drug solution is administered by said second motor is variable (Col. 11, l. 66- Col. 12, l. 7). *Lippe et al.* teaches different delivery modes of operation that could deliver at different speeds.

As to claim 21, *Lippe et al.* discloses an automatic administration instrument as defined in claim 1, further comprising: a microprocessor which outputs instructions to said first motor and said second motor (Col. 14, l. 65- Col. 15, l. 3).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Lippe et al.* [U.S. Patent No. 6,171,276 B1] in view of *Hogan* [U.S. Patent No. 6,406,460 B1].

As to claim 15, *Lippe et al.* discloses all of the limitations of claim 1. *Lippe et al.* does not disclose wherein injection of a drug solution is not carried out when an injection needle is not attached to said body of said administration instrument.

Hogan teaches wherein injection of a drug solution is not carried out when an injection needle is not attached to said body of said administration instrument (Fig. 1).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify *Lippe et al.* such that injection of a drug solution is not carried out when an injection needle is not attached to said body of said administration instrument, as taught by *Hogan*, in order to prevent unintentional needle punctures.

6. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Lippe et al.* [U.S. Patent No. 6,171,276 B1].

As to claims 22 and 23, *Lippe et al.* discloses all of the limitations of claim 1.

As to claim 22, *Lippe et al.* discloses further comprising: a microprocessor which outputs instructions to said first motor and said second motor (Col. 14, l. 65- Col. 15, l. 3).

Lippe et al. does not explicitly teach wherein said first motor rotates in a first direction to drive the syringe such that the injection needle protrudes from said body and rotates in a second direction opposite to the first direction to retract the injection needle into said body. However, at the time of the invention, it would have been obvious to one of ordinary skill in the art that the first motor would operate this way because electrical motor means used for penetration and return means typically functions this way (Col. 15, ll. 4-17).

As to claim 22, *Lippe et al.* discloses further comprising: a microprocessor which outputs instructions to said first motor and said second motor (Col. 14, l. 65- Col. 15, l. 3) and wherein a speed of inserting the injection needle or a speed of pulling out the injection needle is variable (Col. 12, ll. 34-43).

Lippe et al. does not explicitly teach wherein said first motor rotates in a first direction to drive the syringe such that the injection needle protrudes from said body and rotates in a second direction opposite to the first direction to retract the injection needle into said body. However, at the time of the invention, it would have been obvious to one of ordinary skill in the art that the first motor would operate this way because electrical motor means used for penetration and return means typically functions this way (Col. 15, ll. 4-17).

Response to Arguments

7. Applicant's arguments filed 7/6/2010 have been fully considered but they are not persuasive.

Firstly, Applicant argues that claim 1 is patentable over *Lippe et al.* because *Lippe et al.* discloses only one motor and lacks a first motor for driving the syringe in a direction toward the tip of the injection needle. Examiner respectfully disagrees. Examiner believes this is taught in Col. 15, ll. 4-17, where *Lippe et al.* teaches that an electrical motor can be used to control penetration. It is understood that this motor that controls penetration would drive the syringe in a direction toward the tip of the injection needle.

Secondly, Applicant argues that claims 2-10, 15-17, and 21-23 are allowable because they depend from claim 1. Because Examiner does not believe that claim 1 is allowable, Examiner also does not believe that claims 2-10, 15-17, and 21-23 are allowable.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brooke M. Matney whose telephone number is (571)270-1457. The examiner can normally be reached on Monday-Thursday 9AM-7PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571)272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brooke M Matney/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763